K 011322

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DornierMedTech

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Dornier Medical Systems, Inc.'s *SapphireSpot* for Medilas E Laser

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Dornier *SapphireErbium / SapphireSpot* is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices, which includes the following: Dornier *VarioSpot 90* handpiece (K981438) and Asclepion-Meditec's DERMABLATE (K992707).

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Dornier Medical Systems, Inc.
1155 Roberts Boulevard
Kennesaw, GA 30144

Phone: 770-426-1315
Facsimile: 770-514-6288
Date Prepared: August 8, 2001

Contact Person: Tim Thomas

Phone: 770-514-6163
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Name of Device and Name/Address of Sponsor

Dornier *SapphireErbium* handpiece / Dornier *SapphireSpot* handpiece
Dornier Medical Systems, Inc.
1155 Roberts Boulevard
Kennesaw, GA 30144

Classification Name

ER:YAG lasers and their accessories have not been specifically classified by FDA.

Predicate Devices

Dornier *VarioSpot 90* handpiece (K981438)
Asclepion-Meditec's DERMABLATE (K992707).

Intended Use

The Dornier *SapphireErbium* handpiece is intended to be used in general and surgical procedures for incision / excision, vaporization, ablation, and coagulation of soft tissue and cartilage. The Dornier *SapphireErbium* may also be used for laser assisted site preparation for hair transplantation / restoration.

Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, the Dornier *SapphireErbium* and the predicate devices are substantially equivalent and have the same intended use. Based on the technological characteristics and overall performance of the devices, Dornier Medical Systems, Inc. believes that no significant differences exist between the Dornier *SapphireErbium* and the predicate devices, Dornier *VarioSpot 90* handpiece (K981438) and Asclepion-Meditec's DERMABLATE (K992707).

Dornier Medical Systems, Inc. believes the minor differences of the Dornier *SapphireErbium* and its predicate laser devices should not raise any concerns regarding the overall safety or effectiveness.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2001

Mr. Tim Thomas
Director, Regulatory, Quality and
Clinical Affairs
Dornier Medical Systems, Inc.
1155 Roberts Boulevard
Kennesaw, Georgia 30144

Re: K011322
Trade/Device Name: Dornier SapphireErbium/SapphireSpot Handpiece
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 21, 2001
Received: August 22, 2001

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker MD

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 9 2001

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K011322

Device Name: Dornier *SapphireErbium / SapphireSpot* Handpiece

Indications for Use:

The Dornier *SapphireErbium* handpiece is intended to be used in general and surgical procedures for incision / excision, vaporization, ablation, and coagulation of soft tissue and cartilage. The Dornier *SapphireErbium* may also be used for laser assisted site preparation for hair transplantation / ~~restoration.~~

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use _____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011322